



NEWS RELEASE

EFCG WELCOMES THE LATEST REGULATORY ACTION ON APIs BUT ARGUES FOR INCREASED DETERRENCE OF ROGUE PLAYERS

Brussels, 30th September 2008. EFCG - the European Fine Chemicals Group - welcomes the recent announcements and actions taken by the regulatory authorities on both sides of the Atlantic and in Japan to stem the flow of sub-standard and counterfeit APIs and medicines in the wake of the heparin disaster earlier this year.

“While enforcement, and the perception of enforcement, is now becoming much more effective, we must continue to urge the regulators to increase their efforts to deter the rogue players in the API supply chain”, says Guy Villax, EFCG Board member and CEO of Hovione, speaking at CPhI today.

He added, “We are particularly looking forward to the European Commission’s legal proposal to combat counterfeit medicines due in October, as their concept paper included many of the regulatory improvements we have been asking for, especially a much more demanding inspection regime for GMP compliance of API manufacturers in higher-risk countries with lower standards than the EU”.

For many years, EFCG has advocated tougher enforcement of existing laws and new harmonised international laws to combat substandard and counterfeit APIs, many of which are originating from Asia. Whereas also off-patent pharmaceuticals in the past could afford a safety margin, today the profit margins are becoming too narrow to guarantee safety and the risks that competitive pressures drive in off-patent medicines are no longer acceptable.

The majority of pharmaceuticals worldwide are now off patent and the industry has become intensely global and hyper competitive. Never has the need for enforcement been more compelling at ensuring quality and a level playing field.

Weak enforcement has encouraged the growth of severely non-compliant manufacture and sourcing of substandard APIs with fatal effects not only to patients but also to the competitiveness of EU manufacturers of APIs. The majority of APIs sold in the EU now comes from Asia.

Notes for Editors

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EFCG – the European Fine Chemicals Group, www.efcg.cefic.org - is a sector group of Cefic, the European Chemicals Industry Council in Brussels. EFCG provides a forum, a focus and a voice for European fine chemical manufacturers, especially those making APIs and intermediates, to discuss their competitiveness issues and to agree on actions to deal with them.